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ELI LILLY AND COMPANY

By

*KS Broades*

Date

*10-16-03*

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants	:	James A. Hoffmann, et al	)	
Serial No.	:	09/928,198	)	
International Filing Date	:	August 10, 2001	)	Group Art Unit: 1647
For	:	FSH Formulations	)	Examiner: R. Deberry
Docket No.	:	X12383N	)	

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Under the guidelines of 37 C.F.R. 1.97, Applicants submit a copy of each of the documents listed on the attached Form PTO-1449 (modified) for consideration by the Examiner.

Since this Statement is being filed after the period specified in §1.97(b), but before the mailing date of a final action or a notice of allowance, please charge the amount of \$180.00, the fee under 37 C.F.R. 1.17(p), and charge any additional fees which may be required by this or any other related paper, or credit any overpayment to Deposit Account No. 05-0840.

Applicants request consideration of this information.

Respectfully submitted,

*Paula K. Davis*

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16 October 2003

FORM PTO 1449 (modified)

Atty. Docket No.

X12383N

Serial No

09/928,198

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

Applicants

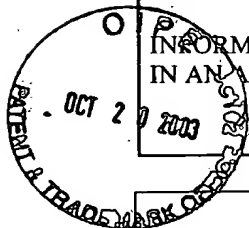
James A. Hoffmann, Jirong Lu

Filing Date

August 10, 2001

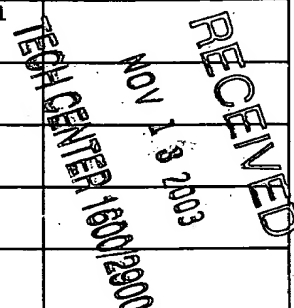
Group

1647



## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Pages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AS	US 4,962,091	Oct. 09 1990	Eppstein, et al	
	AT	US 2003/0072803	Apr. 17 2003	Goldenberg, et al	
	AU	US 6,541,606	Apr. 1 2003	Margolin, et al	
	AV	US 6,267,958	Jul. 31 2001	Andya, et al	



## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	BH	EP 0 891 774	Jan. 2 -1999	Takada, et al		
	BI	WO 98/30592	Jul. 16 1998	Hein, et al		
	BJ	EP 0 668 073	Apr. 14 1999	Igari, et al		
	BK	EP 1 191 099	Mar. 29 2000	Itoh, et al		
	BL	WO 97/17087	May 15 1997	De Young, et al		
	BM	EP 736 303	Aug. 25 1999	Gross, et al		

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicants James A. Hoffmann, Jirong Lu	
	Filing Date August 10, 2001	Group 1647

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T <sup>6</sup>
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## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T <sup>6</sup>
	CBS	Drug Description of Leukine, PDR, pp. 979-983.	
	CBT	Remington's Pharmaceutical Sciences (18th Ed., Mack Publ. Co., 1990, "Parenteral Preparations," pp. 1545-1569).	
	CBU	Maa and Hsu, Intl. J. Pharmaceutics (1996), vol. 140, pp. 155-168.	
	CBV	USP XXI p. 1491 - 1493.	
	CBW	Akers, J. Pharm. Sci. vol. 91, no 11, pp. 2283 - 2300 (2002).	
	CBX	Extract from Handbook of Pharm. Excipients, 3d ed. pp. 41-43 (2000).	
	CBY	Steelman, Endocrinology, vol. 53, pp. 604-616 (1953).	
	CBZ	Hanson & Rouan, Intro to Formulation of Protein Pharmaceuticals, Chap. 7, pp. 209 - 233.	
	CCA	Super-OV (NADA 141-014) label and package insert.	
Examiner Signature	Date Considered		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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